EXHIBIT N

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler Hon. Joel Schneider **DEFENDANTS' FACT SHEET**

In accordance with Case Management Order No. __, within ~~60~~ 90 days of being served with a substantially completed Plaintiff Fact Sheet ("PFS") verified with the required declaration, the [Defendants served with the PFS – (may be subject to revision based on resolution of "macro" discovery issues)] ~~API and finished dose manufacturer Defendants ("Manufacturer Defendants") and any other defendants in the individual case~~ must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel identified in the PFS and on Plaintiffs' Co-Lead Counsel.[1] ~~To the extent necessary to provide complete responses, the Defendants shall confer and share information prior to the deadline for serving their responses..~~ The Defendants will not be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS, which must provide all of the information requested in ~~section~~ Section ~~one~~I of the PFS, including copies of prescription and/or pharmacy records demonstrating use of a Valsartan-containing drug, and, for personal injury plaintiffs, including medical records and/or a certification under oath demonstrating that he or she has been diagnosed with cancer by a licensed physician.

Each served Defendant must complete the section(s) of this DFS that correspond with that Defendant's role(s) in the supply chain for the ~~Valsartan drugs identified in the~~Affected Drugs (defined below). ~~PFS.~~ Each response must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant, or, if applicable, the responding Defendant may produce or cite to produced documents or business records ~~with specificity and~~ by bates number in accordance with Federal Rule of Civil Procedure 33(d).

In filling out this form, Defendants must respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

"AFFECTED DRUGS": The Valsartan-containing drugs purchased by the Plaintiffs that have been identified with specificity in ~~the PFS, and the lot/batch numbers for all Valsartan-containing drugs documented to have been purchased by the Plaintiff, regardless of whether the Plaintiff has identified all lot/batch numbers in the PFS, to be identified by the Pharmacy Defendants~~Sections

[1] Defendants ~~that~~who are subject to the Protocol for Dismissals of Certain Defendants Without Prejudice approved in Case Management Order No. 15 (ECF 247) are excluded from responding to the DFS.

I.B. and -I.C of the PFS and confirmed through Plaintiff's pharmacy records produced pursuant to the PFS.

"DOCUMENTS": "Documents" as used in this request is coextensive with the meaning of the terms "documents," "electronically stored information" and "tangible things" as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent "Documents" refers to electronically stored information, the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

"YOU," "YOUR," or "YOURS": Means the responding Defendant.

I. CASE INFORMATION

This DFS pertains to the following case: _____
Case Name and Docket Number

Date that this DFS was completed: _____

Defendant completing this DFS: _____

II. API MANUFACTURERS

A. Identify whether you ~~are the API manufacturer for~~manufactured the Valsartan API used in any Affected Drug(s) and, if so, which Affected Drug(s)~~, and identify which were contaminated with any nitrosamine or other carcinogenic substance~~.

~~B. For each Affected Drug listed in response to Question II.A, identify all ingredients and raw materials used in the manufacture of the Valsartan API and identify the entities that supplied each.~~

~~C.~~B. For each Affected Drug listed in response to Question II.A, provide the date the API was~~of~~ manufactured and~~,~~ the place of manufacture (by facility, city, state, and country)~~, and the date when the API manufacturing process was completed.~~,

~~D. For each Affected Drug listed in response to Question II.A, identify all entities that supplied any ingredient, solvent, or other material used in the manufacture of these APIs, and state which material, solvent, or ingredient was supplied by each, and which date those supplies or materials were used.~~

~~E.~~C. Identify the entity or entities to which you sold or distributed each Affected Drug identified in response to Question II.A~~,~~ and the date on which each sale or distribution occurred.~~, the price, and all documentation provided to the purchaser or distributor in connection with that sale or distribution.~~

~~F.~~D. For each Affected Drug identified in response to Question II.A, identify (1) any test results from chromatography testing ~~done~~that you conducted on that batch or lot of

API, and (2) any test result that you received from a third party for chromatography done on that lot or batch of API~~of Valsartan drugs that you were provided or conducted (1) to identify impurities, (2) to identify nitrosamines, and/or (3) that identified any impurity or artifact, including but not limited to a nitrosamine, and (4) the full result of that testing~~.

~~G.~~E. State whether you supplied each test result identified in response to Question II.F to the FDA, or to any other entity ~~or person~~named as a Defendant in the applicable Short Form Complaint, and, if so, ~~identify the test result, and~~ provide the recipient~~,~~ of the test result and the date of communication~~, and content~~.

~~H.~~F. Provide the date(s) on which you sent any recall notice that applied to any Affected Drug(s) to any Defendants identified in the ~~PFS~~ applicable Short Form Complaint and attach the recall notice(s).

~~I. Identify all Affected Drugs that you have recalled or otherwise identified as contaminated~~.

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~~J.~~G. ~~J.~~ Have Plaintiff's records identified that ~~Were~~ any Affected Drugs incorporating the Valsartan API that you sold, distributed, labeled, or manufactured in whole or in part ~~by you~~ were ever returned to your possession as a result of a recall letter related to potential NDMA or NDEA impurities, or for allegedly or possibly containing NDMA or NDEA ~~finding or suspicion of contamination~~?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any ~~nitrosamine related~~chromatography testing ~~done~~ you conducted on the returned drugs after they were returned to your possession~~gs~~.

If no, but you have knowledge of the location of the drugs, provide the location:

~~K.~~H. Have you ~~communicated directly with~~contacted Plaintiff directly at any time?

Yes____ No____

If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.

~~L. If you contend that any person, entity, medical condition, food, medication, or product, other than the Defendants and the Affected Drug(s) is a cause of the plaintiff's injuries ("Alternate Cause"):~~

~~1. Identify the Alternate Cause with specificity.~~

~~2. Set forth the date(s) and mechanism of alternate causation.~~

III. FINISHED DOSE MANUFACTURERS

A. Identify whether you are the finished dose manufacturer for any Affected Drug(s) and, if so, which Affected Drug(s)~~, and identify which were contaminated with any nitrosamine or other carcinogenic substance~~.

B. For each Affected Drug identified in response to Question III.A, provide the API manufacturer.

C. For each Affected Drug identified in response to Question III.A, identify the entity or entities to which you sold or distributed each Affected Drug~~,~~ and the date on which each sale or distribution occurred~~., and the price.~~

D. For each Affected Drug identified in response to Question III.A, identify (1) any chromatography testing that you conducted on ~~that batch or lot of Valsartan drugs~~the Affected Drug, or (2) any test result that you received from a third party for chromatography done on ~~that lot or batch of Valsartan drugs~~the Affected Drug.~~done on that batch or lot that you were provided or conducted (1) to identify any impurity, (2) to identify nitrosamines, and/or (3) that identified any impurity or artifact, including but not limited to a nitrosamine, and (4) the full result of that testing.~~

E. State whether you supplied each test result identified in response to Question III.D to the FDA, or to any other entity ~~or person~~named as a Defendant in the applicable Short Form Complaint~~,~~ and, if so, ~~identify the test result, and~~ provide the recipient of the test result and the date of communication~~, date, and content~~.

F. Provide the date(s) on which you sent any recall notice that applied to any Affected Drug(s) to any Defendants identified in the ~~PFS~~ applicable Short Form Complaint and attach the recall notice(s) or cite to them by bates number.

~~G. Identify all Affected Drugs that you have recalled, or otherwise identified as contaminated.~~

~~H.~~G. Have Plaintiff's records identified that ~~Were~~ any Affected Drugs sold, distributed, labeled, or manufactured in whole or in part by you were ever returned to your possession as a result of a recall letter related to potential NDMA or NDEA

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impurities, or for allegedly or possibly containing ~~finding or suspicion of contamination~~NDMA or NDEA?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any ~~nitrosamine related~~chromatography testing you conducted~~ done~~ on the returned drugs after they were returned to your possession.

If no, but you have knowledge of the location of the drugs, provide the location:

~~I.~~H. Have you ~~communicated directly with~~contacted Plaintiff directly at any time?

Yes____ No____

If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.

~~J.~~ Please produce a copy of any adverse event report, including any MedWatch form, ~~which~~ that relates to the Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.

~~K. If you contend that any person, entity, medical condition, food, medication, or product, other than the Defendants and the Affected Drug(s) is a cause of the plaintiff's injuries ("Alternate Cause"):~~

~~1. Identify the Alternate Cause with specificity.~~

~~2. Set forth the date(s) and mechanism of alternate causation.~~

I.

IV. ~~Repackagers, Labelers, Wholesalers, and Distributors~~REPACKAGERS, LABELERS, WHOLESALERS, and DISTRIBUTORS

A. Identify whether you are the repackager, labeler, wholesaler, and/or distributor for any Affected Drug(s) and, if so, which Affected Drug(s)~~, and identify which were contaminated with any nitrosamine or other carcinogenic substance~~.

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Commented [GT1]: Responding Defendants will be identified by their agreed-upon descriptors on the Short Form Complaint. To the extent Plaintiffs are requesting specificity beyond these agreed-upon descriptions these terms will need to be specifically defined in the DFS.

B. For each Affected Drug listed in response to Question IV.A, provide the date of purchase~~,~~ and the entity from ~~whom~~ which the Affected Drug was purchased~~, the purchase price, and the date of purchase~~.

C. For each Affected Drug listed in response to Question IV.A, ~~I~~identify the entity or entities to which you sold or distributed ~~each~~ the Affected Drug ~~identified in response to Question IV.A~~ and the date on which each sale or distribution occurred.

D. For each Affected Drug identified in response to Question IV.A, identify (1) any test results from chromatography testing that you conducted on ~~that batch or lot of Valsartan drugs~~the Affected Drug~~, or (2) any test result that you received from a third party for chromatography done on that lot or batch of Valsartan drugs any testing done on that batch or lot that you were provided or conducted (1) to identify any impurity or artifact, (2) to identify nitrosamines, (3) that identified any impurity or artifact, including but not limited to a nitrosamine, and (4) the full result of that testing~~.

E. State whether you supplied each test result identified in response to Question IV.D to the FDA, or to any other entity ~~or person~~named as a Defendant ~~in the PFS~~in the applicable Short Form Complaint ~~,~~ and, if so, ~~identify the test result, and~~ provide the recipient of the test result and the date of communication~~, date, and content.~~.

~~F. Have you been contacted by communicated directly with Plaintiff directly at any time?~~

~~Yes____ No____~~

~~If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.~~

~~G.~~F. Provide the date(s) on which you sent any type of communication to Plaintiff relating to valsartan-containing drugs and/or a recall of any valsartan-containing drugs.

~~H. Identify all Affected Drugs for which you were involved in the repackaging, sale, wholesaling, or distribution that have been recalled.~~

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~~I.~~G. ~~Were~~ Have Plaintiff's records identified that any Affected Drugs sold, wholesaled, distributed, labeled, or manufactured in whole or in part by you were ever returned to your possession as a result of a recall letter related to potential NDMA or NDEA impurities, or for allegedly or possibly containing~~ finding or suspicion of contamination~~ NDMA or NDEA?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any ~~nitrosamine-related~~chromatography testing ~~done~~ you conducted on the returned ~~drugs~~ Affected Drugs after they were returned to your possession.

~~If no, but you have knowledge of the location of the drugs, provide the location:~~

~~J.~~ Please produce a copy of any adverse event report, including any MedWatch form ~~which~~ that relates to the Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.

~~K. If you contend that any person, entity, medical condition, food, medication, or product, other than the Defendants and the Affected Drug(s) is a cause of the plaintiff's injuries ("Alternate Cause"):~~

~~1. Identify the Alternate Cause with specificity.~~

~~2. Set forth the date(s) and mechanism of alternate causation.~~

H.

V. ~~Pharmacies~~PHARMACIES

A. Identify whether you are the pharmacy that dispensed any Affected Drug(s) and, if so, which Affected Drug(s), and identify which were contaminated with any nitrosamine or other carcinogenic substance.

B. For each Affected Drug listed in response to Question V.A, provide the date of purchase, the entity from whom the Affected Drug was purchased, the purchase price including amounts paid by the consumer and any insurance carrier or other payor, and the location of purchase.

C. For each Affected Drug identified in response to Question V.A, identify any testing done on that lot/batch that you were provided or conducted (1) to identify any impurity or artifact, (2) to identify nitrosamines, (3) that identified any impurity or artifact, including but not limited to a nitrosamine, and (4) the full result of that testing.

D. State whether you supplied each test result identified in response to Question V.C to the FDA, or to any other entity or person, and if so identify the test result, and provide the recipient, date, and content.

E. Have you communicated directly with Plaintiff at any time?

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Commented [GT2]: The Retailer and Pharmacy Defendants will be responding via separate correspondence to Plaintiffs' counsel regarding the Pharmacy-specific obligations set forth in the draft DFS.

Yes____ No____

If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.

F. Provide the date(s) on which you sent any type of communication to Plaintiff or any other person or entity relating to actual or potential contamination of valsartan-containing drugs and/or a recall of any valsartan-containing drugs.

G. Identify all Affected Drugs that you or any entity has recalled, or identified as contaminated or potentially contaminated.

H. Were any Affected Drugs sold by you ever returned to your possession as a result of a recall letter, or finding or suspicion of contamination?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any nitrosamine-related testing done on the returned drugs.

If no, but you have knowledge of the location of the drugs, provide the location:

I. Please produce a copy of any adverse event report, including but any MedWatch form which relates to the Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.

J. If you contend that any person, entity, medical condition, food, medication, or product, other than the Defendants and the Affected Drug(s) is a cause of the plaintiff's injuries ("Alternate Cause"):

1. Identify the Alternate Cause with specificity.

2. Set for the date(s) and mechanism of alternate causation.

~~VI. DOCUMENTS (To be responded to by all defendants)~~

~~A. To the extent you have not already done so, please produce a copy of all documents and things that fall into the categories listed below. These include documents in the possession of any of your present and former employees, including information provided to your attorneys:~~

~~1. Any document created before the filing of this lawsuit which relates to or refers to Plaintiff other than documents received or produced in discovery in this matter.~~

~~2. Subject to limitations set forth in this fact sheet concerning timeframes and categories of relevant information, any document sent to or received from any of Plaintiff's Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physician identified in the PFS.~~

~~3. Communications including "Dear Doctor," "Dear Health Care Provider," "Dear Colleague" letters, or PIRs sent to or received from any of Plaintiff's Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physician identified in the PFS, regarding valsartan.~~

~~4. Subject to limitations set forth in this fact sheet concerning timeframes and categories of relevant information, any and all documents reflecting any contacts or communications between you and any of Plaintiff's Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physician identified in the PFS, regarding valsartan.~~

~~5. Any and all documents which purport to describe, analyze, investigate, track, and/or report the prescribing practices of any of Plaintiff's Prescribing Healthcare Providers identified in the PFS and/or Primary Treating Physician identified in the PFS relating to valsartan subject to the approval and/or agreement of the owner of the prescribing data to release the data, which approval and/or agreement Defendant will request.~~

~~6. Any and all documentation of the information provided in Sections II through V above.~~

VERIFICATION

I am Legal Counsel for _____, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on each corporation's behalf. I hereby certify that the information provided in the accompanying Response to

Defendants' Fact Sheet is not within my personal knowledge, but the facts state therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date:_____ _____
Signature

Name:_____

~~Employer: _____~~

~~Title: _____~~